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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,545	11/12/1999	KENJI SHIBATA	2139.15	6874

5514 7590 01/15/2002

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EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,545

Applicant(s)

SHIBATA ET AL.

Examiner

Anish Gupta

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 2, 6, 8, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Applicant's election of the species of Compound 23, SEQ ID NO. 31 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted for the elected species of SEQ ID. NO. 31. No prior art was found on the elected species and the search was subsequently extended to the peptide corresponding to the peptides of claim 15-16. Prior art was found on the species corresponding to SEQ ID. NO. 5 and an office action corresponding to this species follows below. Claims 1, 2, 6, 8, 15 and 16 read on the elected species. Prior art on a non-elected species corresponding to the markush claim 1 has also been applied.

Claims 3-5, 7, 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-2, 6, 8, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear as to the definition of the variable n_i . In line 15, the claim states that n_i is 1 to 17, however, in line 17 and 18, n_i is defined as 0 or 1. Clarification is requested.

The claims make reference to residues X^p and X^q . However, there is no antecedent basis for these variables in the formula. It is unclear where such residues occur within formula (I) and how these variables affect the structure of the formula.

In claim 1, it is unclear what is being claimed. Claim states that "7 to 17 different Xⁱ's are selected, arranged in order of increasing number of I. . ." It is unclear which one of the Xⁱ's are arranged in this manner. Note that the claim allows for all of the X variable to be Xⁱ. Further, it is unclear how these variables, Xⁱ are related to X^p or X^q.

In claim 1, it is unclear what residues in the formula the statement "one to several residues which are the same or different and selected from the group selected from. . .", at the end of claim 1, is defining. That is, does this definition encompass a specific X variable or amino acids are the N- and C- terminus?

Claim 1 does not utilize proper markush language. Note that the end of claim 1 stats "selected from the group consisting of" but does not use "and." Appropriate correction is required.

In claim 1, it is unclear as to the intent of bracketing and underlining. Bracketing or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Halazonetis et al.

The claims are drawn to cyclic peptide having an activity to restore the DNA-binding activity or the P53 protein-dependent transcription activity to mutant P53 protein.

The reference teaches the peptide cyclo[Ser-Arg-His-Lys-Lys-Ala] (see page 29). This peptide has the ability to activate DNA binding of P53 (see abstract and page 29). The peptide anticipates the claimed invention since the claims allow for deletions and modification of formula (I) in claim 1 in the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 6, 8, 15 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Lane in view of Halzonetis et al.

Lane et al. teach peptides that have the property of activating the sequence specific DNA binding activity of latent P53 (see abstract). The reference teaches that the peptide LKSKKGQSTSRHKKL has this particular activity (see abstract and page 12, line 18-20). The difference between the reference and the instant application is that the reference does not teach the cyclization of the disclosed peptides.

However, Halzonetis et al. teach peptides that have the ability to activate DNA binding of P53 (see abstract and page 29). The reference discloses numerous fragments within the 361-383 residues of human p53. Note, that the peptide of Lane et al. falls within residues 361-383 of p53. Halzonetis et al. also states that the peptide can be cyclized with the expectation of still having activation activity (see page 10, section c). The reference illustrates that cyclization of a linear peptide 378-382 of p53 still activated p53 DNA. Therefore it would have been obvious to cyclize the peptide of Lane et al. and expect the peptide to have the ability to activate DNA binding of p53, as seen in Halzonetis et al.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are

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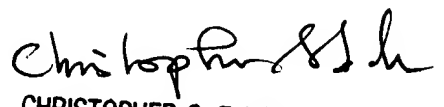
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unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Anish Gupta



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